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10/542,883	12/27/2005	Frederick John Rowell	73551.000002	9715

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EXAMINER	
DIRAMIO, JACQUELINE A	

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1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/542,883	ROWELL, FREDERICK JOHN	
	Examiner	Art Unit	
	JACQUELINE DIRAMIO	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5,6,9,10,21-33 and 35-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5,6,9,10,21-33 and 35-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 July 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/1/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Applicant's amendments to claims 1 and 6 are acknowledged, as well as the cancellation of claims 11 – 18, 20 and 34.

2. Currently, claims 1, 3, 5, 6, 9, 10, 21 – 33 and 35 – 54 are pending and under examination.

Withdrawn Acknowledgement of Allowable Subject Matter

3. After further review of the amendments to the claims, the previous statement over the allowable subject matter, which was previously recited in dependent claim 34 and is now incorporated into independent claim 1, wherein the allowable subject matter involved the use of gravity to move the formed "flowable component," is withdrawn. When considering the claims in view of the prior art, the affinity-chromatography strip of independent claim 1 only requires the structural limitations of a planar surface; a first immobilized component comprising a first bio-reagent and a biopolymer; and a second immobilized component comprising a second bioagent. The rest of the claim limitations are either "optional" or part of the intended use of the device. Therefore, as long as a prior art reference includes the three structural requirements of the planar surface and the first and second immobilized components, the prior art reads on the claimed invention. As discussed below, the previously applied prior art reference of Ching et al. (US 6,534,320), as well as a second newly applied reference, do meet these broad limitations of Applicant's independent claim 1.

Withdrawn Objections and Rejections

4. All previous objections to claims 1 and 6 are withdrawn in view of Applicant's amendments filed March 16, 2009.

5. The previous rejection of claims 1 and 6 under 35 U.S.C. 112, second paragraph, is withdrawn in view of Applicant's amendments filed March 16, 2009.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 3, 5, 6, 9, 10, 21, 23 – 25, 36 – 45 and 54 are rejected under 35 U.S.C. 102(e) as being anticipated by Ching et al. (US 6,534,320).

Ching et al. teach an affinity-chromatography strip, having a longitudinal axis, said strip comprising:

(a) a first immobilized component comprising a labeled first reagent material (bio-reagent) and a meta-soluble protein (biopolymer);

(b) a second immobilized component comprising a second reagent material (bio-reagent); and

(c) optionally a third immobilized component comprising a third reagent material (bio-reagent); wherein said first and second immobilized components are spaced at a first distance

along the longitudinal axis and said third immobilized component, when present, is spaced at a second distance along said longitudinal axis from said second immobilized component; and

wherein, in use, when the strip is immersed in a chromatographic solvent (buffer solution) optionally comprising an analyte (fourth bio-reagent), a flowable component is formed as a discrete volume over said first immobilized component wherein said flowable component:

(i) comprises said first reagent material;

(ii) is denser than the buffer solution;

(iii) does not diffuse rapidly into the buffer solution; and

(iv) slowly rolls over the planar surface of the strip along said longitudinal axis in the direction of said second immobilized component comprising said second reagent material (see Figures 4a-4c; column 6, lines 51-64; column 7, lines 37-62; column 8, lines 60-67; column 9, lines 1-29; column 10, lines 18-62; column 11, lines 13-45; column 15, lines 47-64; column 16, lines 5-67; column 17, lines 1-24; and column 21, lines 14-32).

It is noted that claim 1 requires the limitation that the flowable component flows "under the influence of gravity," however, the limitations recited within the "wherein, in use" clause, all recite intended use limitations. Therefore, given that Ching et al. teach all of the required structural limitations of the planar surface, and the first and second immobilized components, the device of Ching et al. is capable of performing the recited intended use limitations and thus, meets the limitations of the claim.

With respect to Applicant's claims 3, 9, 23, 24, 37, 40, 41, and 43, the labeled first reagent and the second reagent material can comprise antigens and/or antibodies (see column 24, lines 21-38; and Examples 3-6).

With respect to Applicant's claim 5, the flowable component can include a buffer of optimal pH and a detergent (see column 11, lines 30-54; and column 21, lines 14-32).

With respect to Applicant's claim 6, the immobilized component is attracted to the flowable component via the interaction of specific binding (see column 24, lines 21-38; and Examples 3-6).

With respect to Applicant's claims 10, 25, 38, 42, 44, 45, and 54, the label can be colloidal particle or an enzyme-label (see column 11, lines 26-30; and column 25, lines 9-13).

With respect to Applicant's claim 21, the first, second, or third immobilized components can comprise a membrane (see Figures 4a-4c; and column 11, lines 33-41).

With respect to Applicant's claim 36, the analyte (fourth bio-reagent) can comprise an unlabeled antigen (see Example 3-6).

With respect to Applicant's claim 39, the strip discussed above can be included within a kit (see column 10, lines 18-28).

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 3, 6, 9, 10, 21, 23 - 26, 35 – 46, and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by May et al. (US 5,602,040).

May et al. teach an analytical test device (affinity-chromatography strip) having a planar surface and a longitudinal axis, said device (strip) comprising:

(a) a first immobilized component or labeled reagent comprising a first bio-reagent and a sugar (biopolymer);

(b) a second immobilized component comprising a second bio-reagent within a detection zone; and

(c) optionally, a third immobilized component comprising a third bio-reagent within a control zone (see Abstract; Figures 1, 9 and 10; column 2, lines 3-54; column 3, lines 8-45; column 5, lines 8-39; column 6, lines 61-67; and column 7, lines 1-7).

It is noted that claim 1 requires the limitation that "in use, when the strip is immersed in a buffer solution optionally comprising a fourth bio-reagent, a flowable component is formed as a discrete volume over said first immobilized component wherein said flowable component:

(i) comprises said first bio-reagent;

(ii) is denser than the buffer solution;

(iii) does not rapidly diffuse into the buffer solution; and

(iv) slow rolls, under the influence of gravity, over said planar surface along said longitudinal axis in the direction of said second immobilized component comprising said second bio-reagent." However, the limitations recited within the "in use" clause, all recite intended use limitations. Therefore, given that May et al. teach all of the required structural limitations of the claim, which include the planar surface, and the first and second immobilized components, the device of May et al. is capable of performing the recited intended use limitations and thus, meets the limitations of the claim.

With respect to Applicant's claims 3, 9, 23, 24, 26, 36, 37, 40, 41, 43 and 46, the labeled first bio-reagent and the second bio-reagent can comprise antigens and/or antibodies, wherein the first and second bio-reagents can comprise antibodies which bind to a common non-labeled antigen, such as hCG (see column 2, lines 21-67; column 4, lines 18-40; column 9, lines 8-67; and Embodiments 1-5).

With respect to Applicant's claim 6, the first immobilized component is attracted to a flowable component via the interaction of specific binding (see Abstract; and column 4, lines 18-40).

With respect to Applicant's claims 10, 25, 38, 42, 44, 45, and 54, the label can be direct label, such as a colored label, or an indirect enzyme-label (see column 3, lines 22-45; and column 5, lines 27-50).

With respect to Applicant's claims 21 and 35, the first, second and third immobilized components can comprise a nitrocellulose membrane (see Abstract; Figure 1; and column 3, lines 8-21).

With respect to Applicant's claim 39, the strip discussed above can be included within a kit (see column 4, lines 42-45).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ching et al. (US 6,534,320) in view of Yu (US 6,723,500).

The Ching et al. reference, which was discussed in the 102(e) rejection above, teaches that the membrane is wettable, but fails to teach that the membrane is also hydrophobic.

Yu teaches test strips containing a plurality of reaction zones that are defined by a hydrophobic barrier. A hydrophobic composition is utilized to separate the hydrophilic reaction zones contained on the matrix (membrane) of the test strip, in order to create a barrier between each of the reaction zones (see column 10, lines 34-65). The reaction zones contain various compositions to test for one or more analytes. In some embodiments, the test reagents are the same in the reaction zones in order to create a multi-use test strip. In other embodiments, the test reagents are different in the reaction zones to assay for a panel or plurality of different analytes (see column 8, lines 28-40).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a membrane that is both hydrophobic and wettable (hydrophilic) as the membrane in the test strip of Ching et al. as taught by Yu because Yu teaches the benefit of using a hydrophobic composition on a membrane in order to create a barrier between a plurality

of hydrophilic (wettable) reaction zones that each contain a composition to test for one or more analytes of interest.

9. Claims 26, 35, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ching et al. (US 6,534,320) in view of Markovsky et al. (US 2003/0207442).

Ching et al. further fail to teach that said second and third reagent materials (bio-agents) comprise first and second antibodies that specifically bind to a common antigen.

Markovsky et al. teach a test device for detecting the presence of an analyte in a sample, wherein the device includes a sample-absorbing matrix, a support strip, a mobile-phase composition comprising a labeled receptor for the analyte, a test zone comprising a first binder for binding unbound receptor, and a control zone comprising a second binder for binding analyte-bound receptor or residual unbound receptor. By using similar binders, such as antibodies, in both the test and control zones, which can bind to the same antigen, the color or detection signals created in the control and test zones can be compared in order to determine the level of analyte present in the test sample (see Abstract; and paragraphs [0007], [0008], [0010], [0041], [0064] and [0066]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Ching et al. the use of similar antibody binders as the second and third reagents as taught by Markovsky et al. because Markovsky et al. teach the benefit of using similar binders, such as antibodies, in both a test and control zone, which can bind to the same antigen, because the color or detection signals created in the control and test zones can be compared in order to determine the level of analyte present in the test sample.

10. Claims 27 – 31 and 47 – 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ching et al. (US 6,534,320) in view of Markovsky et al. (US 2003/0207442), as applied to claim 26 above, and further in view of Lee et al. (US 7,329,738).

The Ching et al. and Markovsky et al. references fail to teach that the reagents or binders are enzyme labeled antibodies, wherein the first reagent comprises a substrate, in the form of BCIP-NBT and the enzyme comprises alkaline phosphatase.

Lee et al. teach assay methods for detecting and binding to specific surface array proteins of a target analyte. The methods comprise contacting a test sample with a detection reagent, which will bind to the target analyte, wherein the detection reagent preferably comprises an antibody that recognizes the target analyte linked to an enzyme. The antibody is detected when the enzyme reacts with its substrate, producing a detectable product. Preferred enzymes include alkaline phophatase, whose substrate comprises BCIP-NBT. The use of enzyme labels linked to antibodies as the detection reagents allows for the conduction of assay methods outside the laboratory, wherein the labels are readily detectable through visual inspection without the necessity of sophisticated instrumentation (see Abstract; column 2, lines 24-33; and column 12, lines 39-59).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Ching et al. and Markovsky et al. the labeling of the third reagent material with an enzyme, such as alkaline phosphatase, wherein the first reagent material comprises a substrate in the form of BCIP-NBT, as taught by Lee et al. because Lee et al. teach the benefit of utilizing enzyme-labeled antibodies as detection reagents in assays in order to allow for the conduction of assay methods outside the laboratory, wherein the labels

are readily detectable through visual inspection without the necessity of sophisticated instrumentation. In addition, alkaline phosphatase in combination with the substrate BCIP-NBT comprises an exemplary enzyme labeling system for use in assays for the detection of and binding to target analytes.

11. Claims 32 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ching et al. (US 6,534,320) in view of Markovsky et al. (US 2003/0207442), as applied to claim 26 above, and further in view of Miller et al. (US 5,731,157).

The Ching et al. and Markovsky et al. references further fail to teach that the antibodies are specific for savinase.

Miller et al. teach an immunoassay method for detecting specific allergens in test samples. The allergens detected comprise enzymes, such as savinase, which represent airborne allergens that elicit allergic reactions in some individuals after exposure to these enzymes. The enzyme allergens can be detected by utilizing labeled antibodies which specifically bind to the enzyme allergens (see Abstract; Figure 4c; column 1, lines 5-25; column 3, lines 30-35 and lines 62-67; and column 5, lines 21-30).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Ching et al. and Markovsky et al. antibodies specific for savinase as taught by Miller et al. because Miller et al. teach the importance of immunoassay methods which utilize antibodies which bind to specific enzyme allergens, such as savinase, in order to detect various airborne allergens that elicit allergic reactions in some individuals after exposure to these enzymes.

12. Claims 33 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ching et al. (US 6,534,320) in view of Markovsky et al. (US 2003/0207442), as applied to claim 26 above, and further in view of Hubscher et al. (US 2002/0024195).

Ching et al. and Markovsky et al. fail to teach that the meta-soluble protein (biopolymer) comprises dextran or dextran blue.

Hubscher et al. teach a method and lateral flow device for detecting the presence of various analytes. The lateral flow device comprises a membrane with a sample site, gold particles for binding to and labeling the analyte(s) of interest, and a plurality of binding sites for each binding one of a plurality of specific analytes. The binding sites comprise an allergen, which is immobilized through the use of a solubilizing agent, such as a sugar or alcohol, including dextran. The use of sugars or alcohols unfold the allergen protein structure such that more domains are exposed allowing for greater binding to the membrane (see Abstract; and paragraphs [0037], [0038], [0044], [0053], [0054], and [0059]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Ching et al. and Markovsky et al. the use of dextran with the reagent material(s) as taught by Hubscher et al. because Hubscher et al. teach the benefit of using a sugar or alcohol, such as dextran, as a solubilizing agent when immobilizing protein components onto a membrane device because the sugars or alcohols unfold the protein structure such that more domains are exposed allowing for greater binding to the membrane.

Conclusion

13. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACQUELINE DIRAMIO whose telephone number is (571)272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacqueline DiRamio/
Examiner, Art Unit 1641

/Bao-Thuy L. Nguyen/
Primary Examiner, Art Unit 1641
September 8, 2009